Ertoxa

Ertugliflozin L-Pyroglutamic Acid INN

Composition
Ertoxa 5 Tablet: Each film coated tablet contains Ertugliflozin L-Pyroglutamic Acid INN equivalent to Ertugliflozin 5 mg
Ertoxa 15 Tablet: Each film coated tablet contains Ertugliflozin L-Pyroglutamic Acid INN equivalent to Ertugliflozin 15 mg

Pharmacology
SGLT2 is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. Ertugliflozin is an inhibitor of SGLT2 by inhibiting SGLT2, Ertugliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

Indication
Ertugliflozin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosage & Administration
The recommended starting dose of Ertugliflozin is 5 mg once daily, taken in the morning, with or without food • For additional glycemic control, the dose may be increased to 15 mg once daily in patients tolerating Ertugliflozin.

Contraindications
Hypersensitivity reactions such as angioedema to Ertugliflozin or any of it's ingredients. Patients on dialysis.

Warnings and Precaution
Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue, evaluate, and treat promptly. Before initiating, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis • Lower Limb Amputation: Consider factors that may increase the risk of amputation before initiating Ertugliflozin. Monitor patients for infections or ulcers of lower limbs, and discontinue if these occur • Volume Depletion: May result in acute kidney injury. Before initiating, assess and correct volume status in patients with renal impairment or low systolic blood pressure, elderly patients, or patients on diuretics. Monitor for signs and symptoms during therapy • Urosepsis and Pyelonephritis: Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated • Hypoglycemia: Consider a lower dose of insulin or insulin secretagogue to reduce risk of hypoglycemia when used in combination • Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Serious, life-threatening cases have occurred in both females and males. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment • Genital Mycotic Infections: Monitor and treat if indicated.

Adverse Effects
The most common adverse reactions associated with Ertugliflozin are Ketoacidosis, Lower Limb Amputation, Volume Depletion, Urosepsis and Pyelonephritis, Hypoglycemia with concomitant use with Insulin and Insulin secretagogues, necrotizing fasciitis of the perineum and genital mycotic infections.

Interactions
Insulin or Insulin Secretagogues: The risk of hypoglycemia when Ertugliflozin is used in combination with insulin and/or an insulin secretagogue. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with Ertugliflozin.
Positive Urine Glucose Test: SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.
Interference with 1,5-anhydroglucitol (1,5-AG) Assay: Measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Monitoring glycemic control with 1,5-AG assay is not recommended. Use alternative methods to monitor glycemic control.

Use in Pregnancy & Lactation
There are no adequate and well controlled studies of Ertugliflozin in pregnant women. Ertugliflozin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if Ertugliflozin is excreted in human milk. It is not recommended when breastfeeding.

Overdosage
In the event of an overdose with Ertugliflozin, employ the usual supportive measures as dictated by the patient's clinical status. Removal of Ertugliflozin by hemodialysis has not been studied.

Storage
Do not store above 25°C. Protect from light. Keep out of the reach of children.

Packaging:
Ertoxa 5 Tablet: Each box contains 3x10's tablets in blister pack.
Ertoxa 15 Tablet: Each box contains 1x10's tablets in blister pack.

Manufactured by
ZISKA PHARMA
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Kaliakoir, Gazipur, Bangladesh

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Version: 00